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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,729	11/19/2001	Avi J. Ashkenazi	10466/257	1094

35489 7590 10/20/2004

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EXAMINER	
LANDSMAN, ROBERT S	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/989,729	GENENTECH, INC.	
	Examiner	Art Unit	
	Robert Landsman	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *119-127,129-132 and 134-138* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *119-127, 129-132 and 134-138* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/9/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Formal Matters

A. The Amendment dated 9/9/04 has been entered into the record.

B. Claims 119-138 were pending in the application. In the Amendment dated 9/9/04 Applicants canceled claims 128 and 133. therefore, claims 119-127, 129-132 and 134-138 are pending and are the subject of this Office Action.

C. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

2. Priority

A. Applicant asserts that PCT/US00/05841, filed March 2, 2000 discloses a MLR (mixed lymphocyte reaction) assay and that the data generated in the MLR assay establish patentable utility. Applicants also argue that the presently claimed SEQ ID NOs were first disclosed in US Application 60/097,661, filed 8/24/98. However, a review of the instant application and this assay do not lead to a conclusion of utility based on this assay, and therefore, priority to this PCT and/or provision application is not afforded for the reasons of record. The effective filing date of the instant application is still based on present application, filed 11/19/01 for the reasons of record.

3. Information Disclosure Statement

A. The Information Disclosure Statement dated 9/9/04 has been entered into the record. All references have been considered.

4. Specification

A. All objections to the specification have been withdrawn in view of Applicants' amendments.

5. Claim Objections

A. The objection to claims 119-127 and 129-131 has been withdrawn in view of Applicants' amendments to the claims.

B. Claim 134 is objected to since it depends from canceled claim 52.

6. Claim Rejections - 35 USC § 101

A. Claims 119-127, 129-132 and 134-138 remain rejected under 35 USC 101 for the reasons already of record on pages 3-5 of the Office Action dated 3/9/04. Applicants have submitted a Declaration under 37 CFR 1.132 by Dr. Fong. However, this Declaration is insufficient to overcome the holding of lack of utility based on results of the MLR assay. At paragraph #8 of the Declaration, Dr. Fong states "[t]he MLR assay of the present application is designed to measure the ability of a test substance to "drive" the dendritic cells to induce the proliferation of T-cells that are activated, or co-stimulated in the MLR, and thus identifies immune stimulants that can boost the immune system to respond to a particular antigen that may not have been immunologically active previously". This is not what the instant specification asserts at pages 204-206. There is no mention in the instant specification about boosting the immune system "to respond to a particular antigen that may not have been immunologically active previously". It would appear that Dr. Fong is reading the results of the Peterson et al. reference into the disclosure of the instant specification. However, the Peterson et al. reference was not available at the time the instant application was filed, therefore, reliance on the methods and results of this reference is improper.

In paragraph #9 of the Declaration, Dr. Fong states that IL-12 was first identified in an MLR in Gubler et al. (PNAS 88: 4143-4147, 1991). However, a review of Gubler et al. does not reveal the use of MLR in evaluating the biological effects of IL-12. Gubler et al. teach that IL-12 is produced by peripheral blood lymphocytes (predominantly B cells) under appropriate conditions and that IL-12 activates NK cells, facilitates the generation of specific allogeneic CTL responses and stimulates secretion of gamma-interferon. Additionally, IL-12 synergizes with IL-2 to cause the proliferation of resting peripheral blood lymphocytes. Therefore, the further work of researchers regarding IL-12 was not based on the results of a single assay, being the MLR, but rather by a body of work which provides for a number of biological activities of IL-12 which are not disclosed for the claimed invention. The claimed invention is not IL-12. Secondly, the methods of Peterson et al. are not disclosed in the instant specification and are after the filing date of the instant application.

In paragraph 10 of the Declaration, Dr. Fong asserts "a PRO polypeptide shown to stimulate T-cell proliferation in the MLR assay of the present invention with an activity of at least 180% of the control is expected to have the type of activity as that exhibited by IL-12". This is an assertion not supported by any facts or evidence of record. First, the instant specification fails to disclose the degree of activity for the claimed invention in the MLR assay. The specification states that any positive increase over control is considered positive. Therefore, there is no disclosure that the activity in the assay was at least 180%. Secondly, there is no evidence of record which correlates an activity of at least 180% of

control as predictive of an activity of IL-12. It is not clear from what data this conclusion is derived. Therefore, the Declaration is not persuasive to overcome the holding of a lack of utility for the claimed invention based on the MLR assay. It is believed that all pertinent arguments have been addressed.

7. Claim Rejections - 35 USC § 112, first paragraph - enablement

A. Claims 119-127, 129-132 and 134-138 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 5-6 of the Office Action dated 3/9/04. Applicants argue that the present invention is enabled since it possessed utility under 35 USC 101. This argument has been considered, but is not deemed persuasive for the reasons given in the above rejection under 35 USC 101.

B. Claims 119-127, 129-132 and 134-138 remain rejected under 35 USC 112, first paragraph. The Budapest Treaty states that the cell line will be maintained for 30 years, or 5 years from date of last request. Reference to "5 years" has not been disclosed in the specification.

C. Claims 119-123, 132 and 134 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 6-7 of the Office Action mailed 3/9/04. Applicants argue that the claims now recite the functional limitation "wherein said polypeptide encoded by said nucleic acid is an immunostimulant" and that the artisan, given the teachings in the specification, would know how to make and use the present invention. These arguments have been considered, but are not deemed persuasive.

In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

First, the breadth of the claims is excessive with regard to claiming all mammalian sodium channel proteins which are "**at least 80% identical**" to SEQ ID NO:314, or those which "**hybridize**" under stringent conditions to SEQ ID NO:313, including those only 10 bases in length. Nucleic acid molecules which "hybridize" to SEQ ID NO:313 would have one or more nucleic acid substitutions, deletions, insertions and/or additions to the polynucleotide of SEQ ID NO:313. Similarly, proteins which are "at least 80% identical" to the protein of SEQ ID NO:314 would encode for a protein with one or more amino acid substitutions, deletions, insertions and/or additions to the protein of SEQ ID NO:314.

Applicants provide no guidance or working examples of nucleic acid molecules which hybridize to SEQ ID NO:313, or of proteins which are at least 80% identical to SEQ ID NO:314, nor, regarding the hybridization claims, do they provide a *function* of these nucleic acid molecules, or of the proteins which they encode. Regarding all the rejected claims, Applicants have provided no guidance as to what critical residues are required to maintain the functional characteristics of the protein of SEQ ID NO:314. Furthermore, it is not predictable to one of ordinary skill in the art how to make a functional immunostimulant which is less than 100% identical to that of SEQ ID NO:314.

In summary, the breadth of the claims is excessive with regard to Applicants claiming all nucleic acids less than the full length of SEQ ID NO:314. There is also a lack of guidance and working examples of these nucleic acid molecules and proteins as well as which residues are critical for protein function. These factors, along with the lack of predictability to one of ordinary skill in the art as to how to make a functional immunostimulant other that that of SEQ ID NO:314 leads the Examiner to maintain that undue experimentation is necessary to practice the invention as claimed. It is believed that all pertinent arguments have been addressed.

D. No rejection is being made over claim 137 even though it does not recite that the host cell is "isolated." When read in light of the specification, these claims do not read on gene therapy. As defined in the specification "host cells are transfected or transformed with expression or cloning vectors described herein for PRO production *and cultured in conventional nutrient media* modified as appropriate for inducing promoters, selecting transformants, or amplifying the genes encoding the desired sequences" (emphasis added). The fact that these cells are cultured in conventional media demonstrates that these host cells are not transgenic.

8. Claim Rejections - 35 USC § 112, first paragraph – written description

A. The rejection of claims 119-123, 132 and 134 under 35 USC 112, first paragraph, has been withdrawn in view of Applicants' amendments to the claims to recite a functional limitation.

9. Claim Rejections - 35 USC § 112, second paragraph

A. All rejections under 35 USC 112, second paragraph, have been withdrawn in view of Applicants' amendments to the claims.

10. Claim Rejections - 35 USC § 102

A. The rejection of claims 119-127, 128-132 and 134-138 under 35 USC 102 as being anticipated by Baker et al. has been withdrawn in view of the fact that this reference is Applicants' own work and does not disclose, or teach, any more with regard to enablement or utility than that of the present invention.

B. Claims 119-127, 128-132 and 134-138 remain rejected under 35 USC 102 as being anticipated by Fernandez for the reasons already of record on page 9 of the Office Action dated 3/9/04. Applicants argue that, based on the priority date of the present invention, Fernandez is not prior art. This argument has been considered, but is not deemed persuasive since the priority date of the present invention remains 11/24/02 as discussed above.

11. Conclusion

A. No claim is allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (571) 272-0888. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961.

Official papers filed by fax should be directed to (703) 872-9306. Fax draft or informal communications with the examiner should be directed to (571) 273-0888.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-0700.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
October 04, 2004

ROBERT LANDSMAN
PATENT EXAMINER